

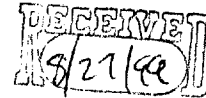


6111 Broken Sound Parkway NW
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August 18, 1999

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204



Dear Sirs:

Notice is hereby given pursuant to Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug and Cosmetic Act that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown brand name bearing the following statement(s) on the label and/or in the labeling:

Calcium XTRA: [It] promotes bone strength. Besides being essential for bones, Calcium is also vital to many other essential body functions. It helps the heart and cardiovascular system by maintaining a regular heartbeat and assists with the transmission of nerve impulses. This Sundown XTRA formula begins with an essential mineral, Calcium, which the body needs for proper health and growth. The ingredients in Sundown Calcium XTRA work in harmony to help promote the building and maintaining of bone mass and bone density.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker
Vice President of Regulatory Affairs
and Assistant General Counsel

Enclosure

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